

§ 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet

the needs of the patients, including those arising from medical and non-medical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See § 405.2102.)

(b) *Standard: On-duty personnel.* Whenever patients are undergoing dialysis:

(1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;

(2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and

(3) An adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102.)

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services—(1) Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in

accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) *Standard: Social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) *Standard: Dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) *Standard: Self-dialysis support services.* The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A recordkeeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(f) *Standard: Participation in recipient registry.* The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 486, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.

(g) *Use of EPO at home: Patient selection.* The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) *Pre-selection monitoring.* The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) *Conditions the patient must meet.* The assessment must find that the patient meets the following conditions:

(i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient;

(ii) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.)

(B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.

(iii) Is under the care of—

(A) A physician who is responsible for all dialysis-related services and who

prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) *Conditions the patient or the patient's caregiver must meet.* The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) *Care and storage of drug.* The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) *Use of EPO at home: Responsibilities of the physician or the dialysis facility.* The patient's physician or dialysis facility must—

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug "on hand" at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

§ 405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§ 405.2130 through 405.2164, with the exception of §§ 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility

is consistent with the patient's long-term program and patient care plan required under § 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§ 405.2102) or a qualified physician-director (§ 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 59 FR 46514, Sept. 8, 1994]

§ 405.2171 Condition: Minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by CMS as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff;